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EXAMINER

MORGAN, ROBERT W

ART UNIT

PAPER NUMBER

3626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 09/893,359	Applicant(s) BECKER ET AL.	
	Examiner Robert W. Morgan	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 27-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/28/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I including claims 1-26 in the reply filed on 5/22/06 is acknowledged. The traversal is on the ground(s) that claims deal with similar subject matter and are classified in the same class and sub-class, and therefor would not be a serious burden on the Examiner. This is not found persuasive because Invention II discloses a method for providing guidance to a clinician for determining a diagnosis and selecting treatments based on authoritative guidelines without constraining the independent practice of medicine by the clinician and Invention III discloses a system for the collecting, integrating, and communicating information related to providing health care, the system linking the clinician with medical records, payor guidelines, reference information, and service providers. As such, Invention II and III would require a different search for examination from that of Invention I, therefore creating a serious and undue burden for the Office.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S.

Patent No. 5,772,585 to Lavin et al.

As per claim 1, Lavin et al. teaches a method of enhancing the quality and efficiency of

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the clinician-patient encounter, the method dependent upon differentiation of two types of data resulting from the clinician-patient encounter, the method comprising:

--the claimed obtaining descriptive data to enable a clinician to determine a diagnosis is met at step 156, where after the appropriate patient file is selected the physician may review the patient demographics, allergy, habits and family history information (see: column 9, lines 9-12). In addition, Lavin et al. teaches that following a basic examination and creation of progress notes, the physician may enter the diagnoses and procedures performed (see: column 9, lines 35-39);

--the claimed determining a diagnosis is met following a basic examination and creation of progress notes, the physician may enter the diagnoses and procedures performed (see: column 9, lines 35-39);

--the claimed entering the diagnosis into an electronic system wherein entry of the descriptive data in an electronic format is not a prerequisite for entering a diagnosis is met by the physician entering progress notes in a structure format including subjective observation and objective observation via a workstation (see: column 9, lines 29-35). In addition, Lavin et al. teaches following a basic examination and creation of progress notes, the physician may enter the diagnoses and procedures performed (see: column 9, lines 35-39). The Examiner considers the diagnosis and descriptive data to be entered independent of one other without needing a prerequisite;

--the claimed automatically determining a proposed plan of action consistent with the diagnosis, the proposed plan of action including one or more elements is met after selecting the disease or diagnosis, the physician has the option of continuing on to selecting the treatment or

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procedure from the custom procedure list (234, Fig. 17) (see: column 13, lines 45-49). The Examiner considers that the customized treatment or procedure list is automatically generated after selecting disease or diagnosis; and

--the claimed electronically displaying the proposed plan of action composed of functional data is met after selecting the disease or diagnosis, the physician has the option of continuing on to selecting the treatment or procedure from the custom procedure list (234, Fig. 17) (see: column 13, lines 45-49 and Fig. 17). Additionally, Lavin et al. teaches that assessment notes listing conclusion are based on the subjective and objective observations, and a treatment plan (see: column 9, lines 29-35).

Lavin et al. fails to explicitly teach:

--the claimed if the proposed plan of action is acceptable to the clinician, accepting the plan of action; and

--the claimed if the proposed plan of action is not acceptable to the clinician, altering or adding to the one or more elements until in order to make them acceptable for the care of a specific patient, wherein the method differentiates between descriptive data and functional data, the descriptive data regarding the patient's history, symptoms and physical examination findings being used by the clinician to form the diagnosis, but only function data being required to be entered into the electronic system to determine a plan of action.

However, Lavin et al. teaches that after selecting the disease or diagnosis, the physician has the option of continuing on to selecting the treatment or procedure from the custom procedure list (234, Fig. 17) (see: column 13, lines 45-49 and Fig. 17). In addition, Lavin et al. teaches that the physician selects a procedure viewed from the list and adds the procedure to the

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procedure table list (230, Fig. 17) (see: column 13, lines 53-55). Furthermore, if a prescription is need the physician is not limited to predetermined dosages and instructions, in addition to allowing the physician to write in a prescription or edit an existing prescription before completed the prescription (see: column 14, lines 12-23). Additionally, Lavin et al. teaches that assessment notes listing conclusion are based on the subjective and objective observations, and a treatment plan (see: column 9, lines 29-35).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made include accepting or editing a treatment plan for a patient based on descriptive data and functional data within the system and method for managing patient medical records as taught by Lavin et al. with the motivation of providing the physician with the proper options and tools to diagnose patients in a efficient and timely manner.

As per claim 2, Lavin et al. teaches the claimed automatically initiating one or more of the action plan elements. This feature is met after selecting the disease or diagnosis, the physician has the option of continuing on to selecting the treatment or procedure from the custom procedure list (234, Fig. 17) (see: column 13, lines 45-49). The Examiner considers that the customized treatment or procedure list (one or more action plan elements) to be automatically initiated after selecting disease or diagnosis;

As per claim 3, Lavin et al. teaches entering the diagnosis into the electronic system includes:

--the claimed entering a colloquial diagnosis into the electronic system is met after viewing the custom diagnosis list or ICD9 list, the physician selects a disease from the list provided (see: column 13, lines 30-43). In addition, Lavin et al. teaches that the physician uses

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CPT95 list, which is a database available from the American Medical Association (see: column 13, lines 30-43);

--the claimed determining from the colloquial diagnosis a formal diagnosis is met after viewing the custom diagnosis list or ICD9 list, the physician selects a disease from the list provided (see: column 13, lines 30-43); and

--the claimed associating the formal diagnosis with said colloquial diagnosis for future use is met after viewing the custom diagnosis list or ICD9 list, the physician selects a disease from the list provided (see: column 13, lines 30-43). In addition, Lavin et al. teaches that the physician uses CPT95 list, which is a database available from the American Medical Association (see: column 13, lines 30-43).

As per claim 14, Lavin teaches the claimed transcribed verbally input data is downloaded to the handheld computing device for review by the clinician. This limitation is met by the physician entering examination data via a voice input data (see: column 2, lines 16-18). In addition, Lavin teaches workstation (14, Fig. 1) can be either fixed or portable to allow physician to enter data, view patient history, and record diagnoses during the examination (see: column 8, lines 59-62).

4. Claims 4-13 and 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,772,585 to Lavin et al. in view of U.S. Patent 6,208,973 to Boyer et al.

As per claim 4, Lavin et al. teaches that the physician selects a procedure viewed from the list and adds the procedure to the procedure table list (230, Fig. 17) (see: column 13, lines 53-55). Furthermore, if a prescription is need the physician is not limited to predetermined dosages and instructions, in addition to allowing the physician to write in a prescription or edit an

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existing prescription before completed the prescription (see: column 14, lines 12-23).

Additionally, Lavin et al. teaches that assessment notes listing conclusion are based on the subjective and objective observations, and a treatment plan (see: column 9, lines 29-35).

Lavin fails to teach:

--the claimed automatically determining whether each the altered or added action plan element is authorized for the entered diagnosis by a payor or other authority; and

--the claimed if the care plan element is not authorized by the payor for the entered diagnosis, automatically suggesting one or more alternative diagnoses for which the care plan element is authorized, thereby allowing a clinician to converge between a diagnosis and plan of action.

Boyer teaches a point of service third party adjudication payment system that once preliminary diagnosis information is entered at step 206, a patient coverage profile returns (automatically) and identifies which treatment are covered based on the insured's policy and patient history at step 208 (see: column 13, lines 42-54).

One of ordinary skill in the art at the time the invention was made would have found it obvious to include automatically suggesting which treatment are covered the insured's policy as taught by Boyer within the system and method for managing patient medical records as taught by Lavin et al. with the motivation of providing a system and method for creation of an adjudication settlement transaction at the point of services which designates the portion of the service to paid by the third party payor and the portion paid by the customer (see: column 3, lines 9-15).

As per claim 5, Lavin et al. teaches a system enhancing the quality and efficiency of the clinician-patient encounter, comprising:

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--the claimed output device for displaying to a clinician, health-related information, including diagnostic and care plan information is met by workstation (14, Fig. 1) that includes display (24, Fig. 1) to display patient record information (see: column 9, lines 3-8 and 25-29);

--the claimed input device for entering diagnostic and care plan information is met by data entry device (26, Fig. 1) of the workstation (14, Fig. 1) (see: column 7, lines 36-40);

--the claimed memory for storing a computer program is met by memory (20, Fig. 1) used to store information about regarding clinical visit (see: column 9, lines 52-57);

--the claimed processor for executing the computer program, the computer program enhancing the quality and efficiency the clinician-patient encounter is met by the system and method includes at least a computer having a processor, memory and data input device and display capable of receiving, manipulating and displaying medical information (see: column 16, lines 3-6):

--the claimed accepting for the clinician a diagnosis entered through the input device is met after selecting the disease or diagnosis, the physician has the option of continuing on to selecting the treatment or procedure from the custom procedure list (234, Fig. 17) (see: column 13, lines 45-49 and Fig. 17);

--the claimed automatically displaying care plan elements consistent with the diagnosis, the care plan elements being arranged in a specific order designated by the clinician and/or an authority is met after selecting the disease or diagnosis, the physician has the option of continuing on to selecting the treatment or procedure from the custom procedure list (234, Fig. 17) (see: column 13, lines 45-49). The Examiner considers that the customized treatment or procedure list is automatically generated after selecting disease or diagnosis; and

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--the claimed accepting from the clinician a selection of one or more alternate or additional care plan elements is met after selecting the disease or diagnosis, the physician has the option of continuing on to selecting the treatment or procedure from the custom procedure list (234, Fig. 17) (see: column 13, lines 45-49). The Examiner considers that the customized treatment or procedure list to be (one or more alternate or additional care plan elements).

Lavin fails to teach:

--the claimed following review and acceptance by the clinician and/or authoritative electronic systems, automatically initiating at least one aspect of the selected care plan elements.

Boyer teaches a point of service third party adjudication payment system that once preliminary diagnosis information is entered at step 206, a patient coverage profile returns (automatically) and identifies which treatment are covered based on the insured's policy and patient history at step 208 (see: column 13, lines 42-54).

The motivations to combine the teachings of Boyer within the system of Lavin are discussed in rejection of claim 4, and are incorporated herein.

As per claim 6, Lavin teaches the claimed care plan elements are displayed in an order determined by the frequency of previous selections by the clinician, an order predefined by the clinician, or an order in accordance with a selected medical authority. This limitation is met by the databases and tables that can be access and analyzed in a variety of ways for example, the program can determine the hierarchy of data enter (see: column 15, lines 47-66). The Examiner considers the analyzing data to determine a hierarchy as displayed in an order of frequencies of previous selection by the clinician, or an order in accordance with a selected medical authority.

As per claim 7, Lavin teaches the claimed program adaptively modifies the order of care

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plan options to reflect choices made by the clinician. This feature is met by the databases and tables that can be access and analyzed in a variety of ways for example, allowing the user to identity trends in patient information (see: column 15, lines 47-59).

As per claim 8, Lavin teaches the claimed accepting from the clinician a selection of one or more care plan elements includes accepting the selection of one or more of the displayed care plans elements. This limitation is met after selecting the disease or diagnosis, the physician has the option of continuing on to selecting the treatment or procedure from the custom procedure list (234, Fig. 17) (see: column 13, lines 45-49). In addition, Lavin et al. teaches that the physician selects a procedure viewed from the list and adds the procedure to the procedure table list (230, Fig. 17) (see: column 13, lines 53-55).

As per claim 9, Lavin teaches the claimed accepting from the clinician a selection of one or more care plan elements includes selecting a revised or additional care plan element or accepting a care plan element that is entered by the clinician and that is not one of the displayed care plan elements. This feature is met by the physician selecting a procedure viewed from the procedure list and/or adds a procedure to the procedure table list (230, Fig. 17) (see: column 13, lines 53-55).

As per claim 10, Lavin et al. teaches that the physician selects a procedure viewed from the list and adds the procedure to the procedure table list (230, Fig. 17) (see: column 13, lines 53-55). Furthermore, if a prescription is need the physician is not limited to predetermined dosages and instructions, in addition to allowing the physician to write in a prescription or edit an existing prescription before completed the prescription (see: column 14, lines 12-23).

Additionally, Lavin et al. teaches that assessment notes listing conclusion are based on the

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subjective and objective observations, and a treatment plan (see: column 9, lines 29-35).

Lavin fails to teach:

-the claimed program further determines whether each entered care plan element is supported by a payor for the entered diagnosis and, if not, displays for selection by the clinician at least one alternative diagnosis for which the payor will support the care plan elements.

Boyer teaches a point of service third party adjudication payment system that once preliminary diagnosis information is entered at step 206, a patient coverage profile returns (automatically) and identifies which treatment are covered based on the insured's policy and patient history at step 208 (see: column 13, lines 42-54).

The motivations to combine the teachings of Boyer within the system of Lavin are discussed in rejection of claim 4, and are incorporated herein.

As per claim 11, Lavin teaches the claimed input device and the output device are positioned on a handheld computer. This limitation is met by the system and method includes at least a computer having a processor, memory and data input device and display capable of receiving, manipulating and displaying medical information (see: column 16, lines 3-6). In addition, Lavin teaches a workstation (14, Fig. 1) can be either fixed or portable to allow physician to enter data, view patient history, and record diagnoses during the examination (see: column 8, lines 59-62).

As per claims 12-13, Lavin and Boyer fail to explicitly teach a wireless communication links to a computer network.

However, Lavin and Boyer teach a workstation (14, Fig. 1) can be either fixed or portable to allow physician to enter data, view patient history, and record diagnoses during the

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examination (see: column 8, lines 59-62). In addition, Lavin and Boyer teach at step 160, that the physician enters progress notes at workstation (14, Fig. 1) choosing voice, text or pen input modes (see: Lavin: column 9, lines 25-29). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a wireless communication links with the system as taught by Lavin and Boyer et al. with the motivation of providing a portable communication link allowing physician to enter and evaluate patient's information in a secure and rapid manner.

As per claim 15, Lavin teaches the claimed program supports one or more applications programming interfaces for communicating with other health-care related programs. This feature is met by multiple clinical personnel and physicians with the ability to access various aspects of common database information using common graphic user interface (see: column 4, lines 4-10).

As per claim 16, Lavin teaches the claimed program communicates with databases accessible through a computer network, thereby permitting the program to recall information from the databases and display the information on the output device. This limitation is met by the network communication that may be controlled using commonly available software as in available from Novell, Inc. (see: column 4, lines 55-59).

As per claim 17, Lavin teaches the claimed database include a medical records database, a payor formulary database and other medical and patient information databases. This limitation is met by the relational database as described in Fig. 24.

Lavin fails to teach:

--the claimed database including payor formularies.

Boyer teaches a provider network database (40, Fig. 2B) that lets health provider (12, Fig.

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1) know what the third party payor (24, Fig. 1) is willing to reimburse for a given patient's healthcare transaction (see: column 9, lines 14-24).

The motivations to combine the teachings of Boyer within the system of Lavin are discussed in rejection of claim 4, and are incorporated herein.

As per claim 18, Lavin teaches the claimed program automatically initiates at least one aspect of the selected care plan by communicating with healthcare service provider programs. This feature is met by the physician selecting a procedure viewed from the list and adds the procedure to the procedure table list (230, Fig. 17) (see: column 13, lines 53-55). Furthermore, Lavin et al. teaches that assessment notes listing conclusion are based on the subjective and objective observations, and a treatment plan (see: column 9, lines 29-35).

As per claim 19, Lavin teaches the claimed service provider program includes one or more pharmacy programs or medical laboratory programs. This limitation is met by the clinical module used by the physician that provides for lab or other customized data tables for display (see: column 14, lines 24-26).

As per claim 20, Lavin teaches the claimed program includes instructions for initiating a page for a clinician's assistant or coworker. This limitation is met when a user first access the system, a main menu display (28, Fig. 2) will presented to the user with several options (see: column 5, lines 47-49).

As per claim 21, Lavin teaches the claimed program causes the display to display patient-related health information upon request of the clinician. This feature is met by the patient information button (32, Fig. 2) used to display patient health information (see: column 5, lines 47-54).

As per claim 22, Lavin teaches the claimed program allows entry of vital sign or other measured patient data manually or via electronic interface into the system. This limitation is met by a nurse or other medical practitioner, may enter the vital sign on a vital statistic entry screen (122, Fig. 12) (see: column 8, lines 39-44).

As per claim 23, Lavin teaches the claimed program causes the display to display the patient's vital signs upon request of the clinician. This feature is met at step 158, where the physician may select a screen to review the vital signs that were entered by the nurse (see: column 9, lines 13-16).

5. Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,772,585 to Lavin et al. in view of U.S. Patent 6,208,973 to Boyer et al. as applied to claims 5 and 24-25 above, and further in view of U.S. Patent 6,687,676 to Denny.

As per claims 24-26, Lavin et al. teaches that the physician selects a procedure viewed from the list and adds the procedure to the procedure table list (230, Fig. 17) (see: column 13, lines 53-55). Furthermore, if a prescription is need the physician is not limited to predetermined dosages and instructions, in addition to allowing the physician to write in a prescription or edit an existing prescription before completed the prescription (see: column 14, lines 12-23). Additionally, Lavin et al. teaches that assessment notes listing conclusion are based on the subjective and objective observations, and a treatment plan (see: column 9, lines 29-35).

Lavin fails to teach the claimed displays advertisements for products or services related to the patient care details as selected by the clinician, determined by the user's professional practice, specialty, location and/or personal interests and context-based manner based on interaction of the clinician with the system.

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Denny teaches prescription verification system that includes screens that provide information regarding the prescription verification system (10, Fig. 1), administrative and advertising, hypertexts links to related Internet web sites and other information beneficial to the use and promotion of the prescription verification system (see: column 7, lines 34-40).

Therefore, it is obvious to a person of ordinary skill in the art at the time the invention was made to include advertisement for products or services as taught by Denny with the system Lavin and Boyer with the motivation of providing a centralized system for health care provider to determine current prescription medical that a specific patient may be using (see: Denny: column 1, lines 52-55).

The system of claim 5 in which the display displays advertisements for products or services related to the patient care details as selected by the clinician.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

In related art Rensimer et al. teaches a system and method for processing patient data to permit physician and other medical staff personnel to record, accurately and precisely patient historical information.

In related art Kraftson et al. discloses a system and method of building and administering a patient management and health care management database containing data relevant to the clinical care of the patient.

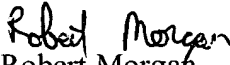
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Morgan whose telephone number is (571) 272-6773.

The examiner can normally be reached on 8:30 a.m. - 5:00 p.m. Mon - Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Robert Morgan
Patent Examiner
Art Unit 3626


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER